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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,472	04/15/2004	Robert H. Zimmer	98204.00024	8345

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,472	ZIMMER, ROBERT H.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26* is/are allowed.

6)☒ Claim(s) *1-17 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/09 has been entered.

Claims 1-17 and 25-26 are under examination.

Response to Amendments/Arguments

Applicant's arguments and amendments, filed 2/27/09, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Information Disclosure Statement

The information disclosure statement, received 2/27/09, is acknowledged. A signed copy is enclosed hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed tothe Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to a pharmaceutical agent having the formula: Carrier-Linker-Peptide.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to conception, synthesis, and experimental protocols and data analysis of experimental results. (2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics: Wherein the peptide is a peptide having the formula aa_n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and combinations thereof and wherein the linker is –C6 or C8 acididic moiety and derivatives thereof.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of a pharmaceutical agent having the formula : carrier-linker-peptide, wherein the peptide is a peptide having the formula aa_n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and combinations thereof and wherein the linker is –C6 or C8 acidide moiety and combinations, pseudopeptides, and peptide mimics thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acidide moiety. The disclosure of a single disclosed species may

provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species of combinations and pharmaceutical agents with an immune sequence characteristic of an infectious, viral or cancerous disease that are not further described and there is substantial variability among the species. No single claim is drawn to a single species which is fully defined.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of derivatives of the carrier and the linker. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that, generally, the more sophisticated that a person of skill in the art would be, the less disclosure is necessary to satisfy the written description requirement. Further, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. Applicant contends that the examiner is improperly attempting to limit the scope of the claims based on the description of certain preferred embodiments.

However, the examiner contends that the present claim encompasses numerous species that are not further described and that there is substantial variability among the species. Absent further disclosure from applicant, a written description rejection is appropriate. Further, the examiner contends that the instant specification must provide an enabling disclosure of the claimed subject matter; mere naming or description of the claimed subject matter is insufficient, if it cannot be produced without undue experimentation. One species of the claimed genus was fully disclosed; wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididic moiety. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species of combinations and pharmaceutical agents with an immune sequence characteristic of an infectious, viral or cancerous disease that are not further described and there is substantial variability among the species. No single claim is drawn to a single species which is fully defined.

Therefore, the claimed invention is deemed to lack adequate written description for the reasons set forth above.

Claims 1-17 and 25 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididc moiety, does not reasonably provide enablement for a pharmaceutical agent having the formula : carrier-linker-peptide, wherein the peptide is a peptide having the formula aa_n , where n is an integer-40, carrier is an aryl or alkyl group and combinations thereof and wherein the linker is –C6 or C13 acididc moiety and combinations, pseudopeptides, and peptide mimics thereof.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a pharmaceutical agent having the formula : carrier-linker-peptide,wherein the peptide is a peptide having the formula aa_n , where n is an integer-40, carrier is an aryl or alkyl group and combinations thereof and wherein the linker is –C6 or C13 acidide moiety and combinations, pseudopeptides, and peptide mimics thereof.

The breadth of the claims is excessive with regard to a pharmaceutical agent having the formula : carrier-linker-peptide,wherein the peptide is a peptide having the formula aa_n , where n is an integer-40, carrier is an aryl or alkyl group and combinations thereof and wherein the linker is –C6 or C13 acidide moiety and combinations, pseudopeptides, and peptide mimics thereof. Applicant has only provided guidance for a peptide is Tyr-Gly-Gly-Phe-Met, carrier is a

cinnamoyl and wherein the linker is –C6 or C8 acididc moiety. Applicant have provided no guidance of any other therapeutic peptide having less than or equal to 40 amino acid residues, or carrier moieties that can be either of a particular chemical species or derivatives thereof.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using a peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididc moiety.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that, generally, the more sophisticated that a person of skill in the art would be, the less disclosure is necessary to satisfy the enablement requirement. Applicant contends that the examiner is improperly attempting to limit the scope of the claims based on the description of certain preferred embodiments.

However, the examiner contends that the present claim encompasses numerous species that are not further described and that there is substantial variability among the species. Absent further disclosure from applicant, a scope of enablement rejection is appropriate. Further, the examiner contends that the instant specification must provide an enabling disclosure of the

claimed subject matter; mere naming or description of the claimed subject matter is insufficient, if it cannot be produced without undue experimentation. One species of the claimed genus was fully disclosed; wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acidide moiety. However, the present claim encompasses numerous species of combinations and pharmaceutical agents with an immune sequence characteristic of an infectious, viral or cancerous disease that are not further described and there is substantial variability among the species. No single claim is drawn to a single species which is fully defined.

Conclusion

Claims 1-17 and 25 are rejected. Claim 26 is found allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
3/24/09

/Christopher R. Tate/
Primary Examiner, Art Unit 1655